

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)
PHARMACY PRODUCTS)
LIABILITY LITIGATION) MDL No. 1:13-md-2419-FDS
)
This Document Relates to:) Judge Rya W. Zobel
)
All Cases)

**DEFENDANT AMERIDOSE LLC'S MOTION TO DESTROY 100 PALLETS OF PAPER
RECORDS PERTAINING TO ITS RECALLED PRODUCTS**

I. INTRODUCTION

Ameridose LLC moves this Court for an Order authorizing the destruction of paper manufacturing records regarding Ameridose products. Although Ameridose has not been operating since the fall of 2012, it is currently storing paper records that are taking up substantial space and will interfere with the use of the facility by future tenants or owners. Importantly, what remains are the manufacturing records of products made well before the recall, as well as records regarding the manufacture of the recalled products that Ameridose destroyed in 2014, pursuant to an Order by this Court and agreement by several of the parties in this litigation. (See, e.g., NECC MDL Docket Nos. 1090, 1138). Because these paper records do not pertain to MPA and no lawsuit has been brought against Ameridose for any product that it manufactured, Ameridose respectfully moves this Court for an order allowing it to destroy the records.

II. RELEVANT FACTS

Ameridose manufactured approximately 2,500 products. It kept manufacturing records of every batch of every product. The product at issue in this MDL, however, is

methylprednisolone acetate (“MPA”), which was compounded and dispensed by NECC.¹ It is undisputed that Ameridose LLC did not compound, manufacture, dispense, or distribute MPA, the drug allegedly responsible for the 2012 fungal meningitis outbreak. In October 2012, Ameridose ceased operations, and on October 31, 2012, Ameridose voluntarily recalled all (approximately 2,500) of its products. (See Affidavit of Ingrid Martin at ¶ 3, attached as Exhibit A and <http://www.fda.gov/Safety/Recalls/ucm326349.htm> (Press Release Announcing Recall)).

In April 2014, Ameridose moved this Court for an Order to destroy its inventory of recalled products. (NECC MDL Docket No. 1090; *see also* Ex. A., Martin Affidavit at ¶ 4). On May 22, 2014, this Court granted the motion, in part, as to the destruction of “controlled substances.” (NECC MDL Docket No. 1138; *see also* Ex. A., Martin Affidavit at ¶ 4). Immediately thereafter, Ameridose, under FDA’s supervision, destroyed those “controlled substances.” (Ex. A., Martin Affidavit at ¶ 5). Later, pursuant to agreement by the Plaintiffs’ Steering Committee, the Tennessee Clinic Defendants, and Unifirst Corporation, Ameridose destroyed the remaining recalled products. (*Id.*).²

Since Ameridose ceased operations in 2012, it has been functionally out of business. Despite this, Ameridose has continued to store 100 pallets of paper records regarding the manufacture of Ameridose drug products in an effort to comply with any arguable preservation obligations as outlined by this Court in December 2012. (*Id.* at ¶ 8; *see also* NECC MDL Docket No. 111). These paper records are the manufacturing records of drugs made before the recall and are records of recalled products that Ameridose destroyed pursuant to an Order by this

¹ There are only two or three cases alleging a defect in a different NECC product.

² Also, in October 2014 Ameridose filed a Notice Regarding the Disposition of Assets in which it, in consultation with the Trustee, notified all parties to this litigation that, in accordance with the May 2, 2014 Plan Support and Funding Agreement, it intended to sell or otherwise dispose of all remaining Ameridose property and to vacate the Westborough facility. (NECC MDL Docket No. 1501). Thus, with the exception of the paper records at issue, Ameridose has essentially sold or otherwise disposed of its property and vacated the Westborough facility.

Court and agreement by several of the parties in this litigation. Like the recalled products that Ameridose destroyed in 2014, none of these paper records pertain to MPA. (Ex. A., Martin Affidavit at ¶ 9). Nor do these paper records pertain to the formulation or production of any product that is the subject of any Complaint filed by a plaintiff in any civil lawsuit. (*Id.*). Indeed, to date, not a single case in the MDL alleges that a specifically identified Ameridose product was contaminated and caused harm. (*See id.*). And to the extent Ameridose has ever had out-of specification test results of its products, those test results and follow-up records are not included in what Ameridose seeks to destroy by this Motion.

Ameridose is currently in the process of leasing or selling its facility to unrelated entities, which will require it to clear out as much space as possible. (*Id.* at ¶ 7). To complete the sale or lease of its facility, Ameridose requests this Court issue an order allowing it to destroy the 100 pallets of paper records it is currently storing.

III. LAW AND ARGUMENT

A. This Court Has the Authority to Permit the Destruction

This Court should exercise its authority to allow Ameridose to destroy the 100 pallets of paper records it is currently storing at its facility. Courts are invested with broad inherent powers to manage all phases of a litigation so as to achieve the orderly and expeditious disposition of cases. *See McGuire v. Acufex Microsurgical, Inc.*, 175 F.R.D. 149, 153 (D. Mass. 1997) (quoting *Chambers v. NASCO, Inc.*, 501 U.S. 32, 43 (1991)); *Citizens for Consume v. Abbott Labs.*, No. 01-12257-PBS, 2007 WL 7293758 (D. Mass. Mar. 26, 2007). Specifically, courts have the authority to order that evidence be preserved and may impose sanctions on a party for

its failure to preserve evidence. *Id.*; see also *Pueblo of Laguna v. United States*, 60 Fed. Cl. 133, 135 (2004).³

Similarly, courts have ordered that potential evidence be destroyed if the circumstances indicate that the evidence need not be preserved. *See, e.g., In re: Pet Food Prods. Liab. Litig.*, 345 Fed. App'x. 857, 859 (3d Cir. 2009) (ordering destruction of recalled inventory by granting protective order allowing defendants to destroy all but a sampling of recalled inventory); *Brandner v. Abbott Labs., Inc.*, No. 10-3242, 2011 WL 2457683, *4 (E.D. La. June 16, 2011) (same); *In re: Digitek Prod. Liab. Litig.*, MDL No. 1968 (S.D. W. Va. Mar. 10, 2010) (ordering destruction of non-Digitek recalled product) (unpublished Pretrial Order #55, attached as Exhibit B). Factors courts consider in determining whether evidence can be destroyed are the cost and undue burdens posed with maintaining the evidence and the particular circumstances in each case that may warrant the destruction of the evidence. *See, e.g., Brandner*, 2011 WL 2457683 at *3-4.

Here, the cost-benefit analysis indicates the paper records need not be preserved. As an initial matter, the preservation and storage of the paper records imposes substantial operational and financial burdens on Ameridose or its owners. Subsequent owners or tenants cannot use the substantial space currently housing 100 pallets of paper records. This is important considering Ameridose is currently in the process of selling or leasing its facility and cannot complete this process until it destroys the records. (Ex. A., Martin Affidavit at ¶ 7). Paying for storage elsewhere is simply not feasible under these circumstances.

³ Other jurisdictions are in accord with the proposition that courts have the inherent power to manage the preservation of evidence. *See U.S. v. Salad*, 779 F. Supp. 2d 503, 507-08 (E.D. Va. 2011); *United States v. Boeing Co.*, No. Civ. A. 05-1073-WEB, 2005 WL 2105972, *2 (D. Kan. Aug. 31, 2005); *Capricorn Power Co., Inc. v. Siemens Westinghouse Power Corp.*, 220 F.R.D. 429, 431 (W.D. Pa. 2004).

Ameridose is a settled defendant, and claims against it are now barred by the channeling injunction. The PSC and Ameridose are working on plans for the dismissal of these cases. There is simply no benefit to forcing Ameridose to continue to incur financial burdens to preserve the paper records. They are wholly irrelevant to what happens next in this litigation. Critically, Ameridose has not been sued over any of *its own products*. No plaintiff in this litigation has expressed an interest in the paper records. Ameridose's counsel approached the Tennessee Clinic Defendants about this issue, but they never responded. Requiring Ameridose to continue to store paper manufacturing records of drug products not at issue in this litigation will only further perpetrate the unnecessary operational and financial burdens frowned upon by the *Brandner* court.

IV. CONCLUSION

Ameridose has diligently preserved paper records in an abundance of caution to comply with any arguable preservation obligations in this litigation, even though it never designed, compounded, manufactured, or distributed MPA, the drug that is allegedly responsible for the meningitis outbreak. Preserving these records of manufacturing drug products not at issue in the MDL has and will continue to impose material operational and financial burdens on Ameridose. Accordingly, Ameridose should be relieved of its obligation to preserve these paper records and respectfully requests that the Court issue an order allowing it to destroy them.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on June 18, 2015 using the ECF system that sent notification of this filing to all ECF-registered counsel of record via e-mail generated by the Court's ECF system.

/s/ Matthew P. Moriarty

Attorney for Defendant Ameridose, LLC